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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,432	05/11/2001	Grace Wong	49853 (72024)	7247

7590 04/04/2002

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EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/04/2002

21

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/854,432	<b>Applicant(s)</b> WONG, GRACE	
	<b>Examiner</b> Ruixiang Li	<b>Art Unit</b> 1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 January 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-11 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 and 3, drawn to a method for identifying an agent which modulates an TNF & IFN influenced cellular process or response by determining *the level of expression* of one or more TNF & IFN stimulated genes, classified in class 435, subclass 6.
- II. Claims 2 and 4, drawn to a method for identifying an agent which modulates an TNF & IFN influenced cellular process or response by determining *the activity of the product* of one or more TNF & IFN stimulated genes, classified in class 436, subclass 510.
- III. Claims 5, drawn to a method for detecting or monitoring a cellular process or response that is influenced by TNF & IFN by determining *the level of expression* of one or more TNF & IFN stimulated genes, classified in class 435, subclass 6.
- IV. Claims 6, drawn to a method for detecting or monitoring a cellular process or response that is influenced by TNF & IFN by determining *the level of activity of the product* of one or more TNF & IFN stimulated genes, classified in class 436, subclass 510.
- V. Claim 7, drawn to a method for assessing whether cells will be responsive to an agent which modulates an TNF & IFN influenced cellular process or response by determining *the level of expression* of one or more TNF & IFN stimulated genes

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in the sample exposed to the agent and in a sample of cells that is not exposed to the agent, classified in class 435, subclass 6.

VI. Claim 7, drawn to a method for assessing whether cells will be responsive to an agent which modulates an TNF & IFN influenced cellular process or response by determining *the level of activity of the product* of one or more TNF & IFN stimulated genes in the sample exposed to the agent and in a sample of cells that is not exposed to the agent, classified in class 436, subclass 510.

VII. Claims 9 and 10, drawn to a method for modulating an TNF & IFN influenced cellular process or response, classified in class 435, subclass 6, and class 436, subclass 510.

VIII. Claim 11, drawn to a method of treating a viral disease, disorder or infection, classified in class 435, subclass 6, and class 436, subclass 510.

2. The inventions are distinct, each from the other for the following reasons. Inventions I-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instance case the different inventions are drawn to completely different methods each having completely different method steps, using different compositions, and having completely different outcomes. First, methods for identifying an agent which modulates an TNF & IFN influenced cellular process or response by determining the level of expression of one or more TNF & IFN stimulated genes or by determining the activity of the product of one or more TNF & IFN stimulated genes can not be used

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for detecting or monitoring a cellular process or response that is influenced by TNF & IFN. Nor will it provide information on the methods for assessing whether cells will be responsive to an agent which modulates a TNF & IFN influenced cellular process or response, for modulating an TNF & IFN influenced cellular process or response, or for treating a viral disease. And vice versa, methods of modulating a TNF & IFN influenced cellular process or response, disease treatment, or detecting/monitoring a cellular response that is influenced by TNF & IFN will not provide information on methods for identifying an agent that modulates a TNF & IFN influenced cellular process or response. Finally, a method comprising measurement of the level of expression of one or more TNF & IFN stimulated genes and a method comprising measurement of the activity of the product of one or more TNF & IFN stimulated genes are exclusive because the two methods have different method steps and determining different products, one measuring nucleic acids, whereas the other measuring the activity of proteins. Thus, all the methods are exclusive.

3. Because these inventions are distinct for the reasons given above and the search required for a single group is not required for any other group, restriction for examination purposes as indicated is proper.
4. This application contains claims directed to patentably distinct species: TNF & IFN stimulated genes listed in Tables 1 and 2. These species require non-cohesive searches and considerations.

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Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02 (a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Elizabeth C. Kemmerer*

Ruixiang Li  
Examiner  
April 2, 2002

ELIZABETH KEMMERER  
PRIMARY EXAMINER